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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/618,531

07/11/2003

Philip A. Furman

04674.105074 (TRI 1016)

6903

20786

7590

10/17/2006

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EXAMINER

JAGOE, DONNA A

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 10/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/618,531	<b>Applicant(s)</b> FURMAN, PHILIP A.	
	<b>Examiner</b> Donna Jagoe	<b>Art Unit</b> 1614	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-8 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>2/13/04 and 8/10/04</u> . | 6) <input type="checkbox"/> Other: ____  |

## **DETAILED ACTION**

***Claims 1-8 are presented for examination.***

### ***Claim Objections***

The use of the trademark SuperFeron and HuFeron has been noted in claim 5. A trademark name should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 1, drawn to the terms  $\beta$ -L-FTC and L-FMAU, it is customary that the full name of the abbreviation be recited the first time the abbreviation is used in the claims. The meaning of every term used in a claim should be apparent from the prior art or from the specification and drawings at the time the application is filed. Applicants need not confine themselves to the

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terminology used in the prior art, but are required to make clear and precise the terms that are used to define the invention whereby the metes and bounds of the claimed invention can be ascertained. During patent examination, the pending claims must be given the broadest reasonable interpretation consistent with the specification. In re Morris, 127 F.3d 1048, 1054, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997); In re Prater, 415 F.2d 1393, 162 USPQ 541 (CCPA 1969).

The remaining claims are indefinite to the extent that they read on the rejected base claims.

***Claim Rejections - 35 USC § 102***

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by  
Schinazi et al. U.S. Patent No. 5,703,058 A.

Schinazi et al. teach FTC exhibits activity against Hepatitis B virus (HBV) (column 2, lines 40-41) and genetically engineered vaccine, alpha interferon effective for HBV (column 2, lines 46-55). Schinazi et al. further disclose that L(-)FMAU is another example of an antiviral agent that can be used in combination with the (-) enantiomer of FTC (column 6, lines 21-27) for the treatment of HBV infections in humans (column 3, lines 5-6).

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***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schinazi et al. U.S. Patent No. 5,703,058 A and Thyagarajan U.S. Patent No. 6,589,570 B1.

Schinazi et al. teach FTC exhibits activity against Hepatitis B virus (HBV) (column 2, lines 40-41) and genetically engineered vaccine, alpha interferon effective for HBV (column 2, lines 46-55). Schinazi et al. further disclose that L(-)FMAU is an example of an antiviral agent that can be used in combination with the (-) enantiomer of FTC (column 6, lines 21-27) for the treatment of HBV infections in humans (column 3, lines 5-6).

Schinazi et al. does not teach the  $\beta$ -L-FTC is substantially pure and it does not teach the many variations of interferon.

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In general, stereoisomers/optical isomers are obvious from racemic mixtures. As legal authority the examiner cites *In re Adamson and Duffin*, 125 U.S.P.Q. 233. The case sets forth the requirements of patentability with regard to stereoisomers as follows:

1) The existence of a racemate is, in and of itself, sufficient to render obvious any individual stereoisomers contained within; no express suggestion of isomer separation is needed. See the first paragraph on page 235.

2) One skilled in the art expects that individual stereoisomers will differ significantly in physiological/pharmacological activity and toxicity, because living systems are chiral and thus preferentially process stereochemical configurations over others. See page 234, the third full paragraph and page 235, the fifth full paragraph on the page.

L-FTC is known from the recitation of its use for treatment of HBV in U. S. Patent 5,703,058. Consonant with the reasoning of *Adamson*, the existence of that racemate renders obvious any individual stereoisomers contained within, i.e. the R and S enantiomers recited instantly. Regarding the substantially pure form of  $\beta$ -L-FTC, Schinazi et al. teach that the  $\beta$ -L forms are specifically contemplated (column 7, line 64 to column 8, line 3). Schinazi teach that enantiomerically pure forms are used herein and the term enantiomerically enriched refers to a nucleoside composition that includes at least 95% to 98% of a single enantiomer of that nucleoside (column 6, lines 45-49). One skilled in the art would have been motivated to prepare additional useful compositions of the ranges taught by the prior art. While the reference is silent regarding the 90% by weight ratios, the

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difference in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. When the general conditions are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. In re Aller, 220 F.2d 45, 105 USPQ 233, 235 (CCPA 1955). In the absence of any criticality and/or unexpected results of the additional ranges claimed, the instant invention is considered obvious.

Regarding the method of use of alpha, beta and gamma interferon for the method of treating hepatitis B, Thyagarajan (quoting Lau et al., Gut. Suppl. 1991;547-562) recites in Table 1 (column 2), agents that have been studied and are successful in the treatment of HBV infection are *inter alia* Interferons such as Alpha interferon, Beta interferon and Gamma interferon.

It would have been made obvious to one of ordinary skill in art at the time it was made to employ the combination of  $\beta$ -L-FTC and L-FMAU and interferon for the treatment or prophylaxis of a human infected with hepatitis B virus motivated by the teaching of Schinazi et al. who recites that L(-)FMAU is an example of an antiviral agent that can be used in combination with the (-) enantiomer of FTC (column 6, lines 21-27) for the treatment of HBV infections in humans (column 3, lines 5-6) along with alpha interferon (column 2, lines 46-55) and the teaching of Thyagarajan who recites that Interferons such as Alpha interferon, Beta interferon and Gamma interferon are successful treatments for HBV.

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Thus the claims fail to patentably distinguish over the state of the art as represented by the cited references.

Accordingly, for the above reasons, the claims are deemed properly rejected and none are allowed.

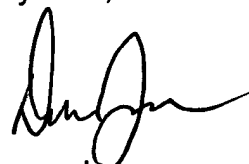
### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday through Thursday from 9:00 A.M. - 3:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Donna Jagoe  
Patent Examiner  
Art Unit 1614

September 30, 2006



ARDIN H. MARSCHEL  
SUPERVISORY PATENT EXAMINER